

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

**THE CITY OF HUNTINGTON,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01362

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**CABELL COUNTY COMMISSION,
Plaintiff,**

v.

CIVIL ACTION NO. 3:17-01665

**AMERISOURCEBERGEN DRUG
CORPORATION, et al.,
Defendants.**

**PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR
PARTIAL SUMMARY JUDGMENT CONCERNING
DEFENDANTS' STATUTORY AND REGULATORY DUTIES**

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INTRODUCTION

Defendants argue that the CSA and its implementing regulations do not impose any duties on registrants, much less a duty to halt opioid shipments pending a due diligence investigation to establish that diversion is unlikely. This argument has been unanimously rejected by every federal court to consider the question, holding that, as a matter of statutory and regulatory construction, the duty to maintain effective controls against diversion cannot be met if registrants are permitted to ship orders they know to be suspicious without first determining that the orders are unlikely to be diverted.¹ Contrary to Defendants' arguments, the no-ship duty exists (along with the duties to identify and report suspicious orders) and resolving this question of law is ripe for adjudication in this motion for partial summary judgment.²

¹ See *Masters Pharmaceuticals Inc., Decision and Order*, 80 FR 55418-01, 2015 WL 5320504 (DEA September 15, 2015), *aff'd*, *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213, 222 (D.C. Cir. 2017); *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3917575, at *7-9 (N.D. Ohio Aug. 19, 2019)(Exhibit A to opening brief); *City and County of San Francisco v. Purdue Pharma, LP, et al.*, No. 3:18-CV-07591-CRB, 2020 WL 5816488 at *3-4 (N.D. Cal. Sep. 30, 2020)(Exhibit 1).

² For the reasons set forth in Plaintiffs' Memorandum in Support of Motion to Adopt Multidistrict Litigation Court's Order on Defendants' Controlled Substances Act Duties, Judge Polster's decision in *In re Nat'l Prescription Opiate Litig.*, *supra*, should independently be adopted based on the law of the case doctrine as no changed or unusual circumstances are present here. See Doc. 190 at 4-9.

ARGUMENT

I. PLAINTIFFS' MOTION IS PROCEDURALLY PROPER.

Plaintiffs' motion for partial summary judgment seeks resolution by the Court of the scope of Defendants' duties pursuant to the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801 *et seq.*, and the West Virginia Controlled Substances Act ("WVCSA"), W.Va. Code §§ 60A-8-1 *et seq.*³ Defendants contend that because Plaintiffs do not seek a ruling that would dispose of an entire claim or defense, Plaintiffs' motion is not properly before the Court, and that any ruling on these issues would be advisory.⁴

Defendants simply ignore the 2010 amendments to Rule 56. Rule 56(a), as amended in 2010, provides that “[a] party may move for summary judgment, identifying each claim or defense — *or the part of each claim or defense* — on which summary judgment is sought.”⁵ The 2010 Amendment to Rule 56(a) made explicit the availability of a motion for partial summary judgment with respect to a “part of each claim or defense.”⁶ Summary judgment is particularly appropriate when the

³ Defendants concede that the WVCSA is intended to be interpreted consistent with the federal CSA to the fullest extent practicable, Opp. at 6, and offer no arguments that the WVCSA should be interpreted differently than the CSA. Consequently, Plaintiffs address only the CSA in this Reply and urge the Court to reach a consistent interpretation of the WVCSA.

⁴ Opp. at 2-4, 20.

⁵ Fed. R.Civ. Pro. 56(a) (emphasis added).

⁶ See Advisory Committee Note to the 2010 Amendment to Rule 56 (“The first sentence is added to make clear at the beginning that summary judgment may be requested not only as to an entire case but also as to a claim, defense, or part of a claim or defense.”).

issue involves statutory interpretation presenting a “question of law for the court to decide.”⁷

As evidenced by the summary judgment briefing before the Court, the parties vigorously disagree as to the scope of the duties imposed by the CSA. Defendants, however, recognize that a violation of a statute, such as the CSA, is a factor to consider in a public nuisance claim.⁸ Indeed, whether the Defendants’ conduct violated the law is one of the elements of the public nuisance claim Plaintiffs are explicitly bringing in this action.⁹ In granting a nearly identical motion, Judge Polster recognized the suitability of summary judgment to decide this question because it does not involve any facts – disputed or otherwise.¹⁰ This is not a hypothetical or advisory question. The scope of the duties imposed on registrants is a question of law requiring construction of the statute, the regulations, and the DEA’s rulings with respect to them. A ruling on this issue will determine the legal framework for a portion of Plaintiffs’ claim and thus will guide the parties in their

⁷ *Willits v. City of Los Angeles*, 925 F. Supp. 2d 1089, 1092 (C.D. Cal. 2013); *see also Reider v. Philip Morris USA Inc.*, No. 3:09-cv-10465-J-32JBT, 2013 WL 12157871, at *2 (M.D. Fla. June 3, 2013) (summary judgment particularly appropriate where parties present questions of law).

⁸ Opp. at 3.

⁹ *See* Plaintiffs’ Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims, Doc. 1075 at 9-16 (Oct. 6, 2020).

¹⁰ *In re Nat’l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3917575, at *1 (N.D. Ohio Aug. 19, 2019).

presentation of evidence at trial.¹¹ The issue is properly before the Court for review and determination.

II. THE CSA AND THE WVCSA REQUIRE DEFENDANTS TO IDENTIFY AND REPORT SUSPICIOUS ORDERS AND TO HALT SHIPMENTS OF SUCH ORDERS PENDING INVESTIGATION.

Three different federal courts have recognized that Defendants have a duty to halt and investigate suspicious orders prior to shipping.¹² Judge Polster's decision in the MDL and the D.C. Circuit's decision in *Masters Pharmaceutical, Inc.* were addressed in Plaintiffs' opening memorandum. More recently, in *City & County of San Francisco, supra*, Judge Breyer confirmed the existence of the duties in a decision ignored by Defendants. Specifically, Judge Breyer held: "The CSA and its implementing regulations do impose duties on Defendants...The MDL court concluded that these regulations impose duties on manufacturers and distributors to identify, report, and refrain from shipping suspicious orders...This Court...adopts the MDL court's conclusions on this issue and rejects Defendants' argument that the CSA's implementing regulations do not impose legal duties."¹³

Defendants' suggestion, rejected by every federal court to consider the issue, that once suspicious orders have been identified, a registrant's only obligation is to

¹¹ In addressing these Defendants' motions to dismiss, Judge Breyer recognized the importance of the question and decided the scope of the CSA duties first "because several other issues turn on the question whether the CSA imposes such duties." *City & County of San Francisco*, 2020 WL 5816488, at *3. And, Judge Polster expressly rejected the argument that evidence of CSA violations are irrelevant, holding that "evidence of the Defendants alleged CSA violations is relevant to the . . . public nuisance claims." MDL Doc. 3052 at p. 26. (Exhibit 2).

¹² See *supra* note 1.

¹³ *City & County of San Francisco*, 2020 WL 5816488, *3-4 (emphasis in original).

report those orders to the DEA, should be also rejected by this Court. The position is legally, logically, and morally indefensible. Rather, as explained below, the duty to provide effective controls against diversion, coupled with the duty to identify suspicious orders, necessarily entails that registrants suspend suspicious orders pending a “due diligence” investigation to determine whether the order is likely to be diverted.

A. The CSA, its Implementing Regulations, and the Official Pronouncements of the DEA all Support Recognizing the No-Ship Duty.

The CSA provides that, “[e]xcept as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally - to manufacture, distribute, or dispense a controlled substance.”¹⁴ The statute authorizes the DEA to promulgate regulations pursuant to which controlled substances may be lawfully manufactured and distributed.¹⁵ The DEA has promulgated a regulation that explicitly requires all registrants under the CSA to “provide effective controls and procedures to guard against theft and diversion of controlled substances.”¹⁶ As explained in Plaintiffs’ opening brief, and as discussed below, this regulation gives rise to Defendants’ duty to halt and investigate suspicious orders.

This duty is simply a corollary of the duty to maintain effective controls against diversion; there can be no such controls if Defendants can ship orders they

¹⁴ 21 U.S.C. § 841(a).

¹⁵ 21 U.S.C. § 821. Contrary to Defendants’ suggestion, Opp. at 13, n.18, this provision authorizes the DEA to promulgate regulations regarding the distribution of controlled substances.

¹⁶ 21 C.F.R. § 1301.71(a).

know (or should know) to be suspicious. As Judge Polster and Judge Breyer both found, Defendants have a duty to halt shipment and investigate suspicious orders.¹⁷ As explained in Plaintiffs' opening brief, the DEA has twice held, in formal adjudications in the *Masters* and *Southwood* cases, that the CSA and the regulations impose the no-shipping duty.¹⁸ Defendants ask this Court to disregard these decisions, arguing that they are neither legal precedent nor entitled to deference.¹⁹ Defendants are wrong.

To begin with, *Masters* is not merely an agency determination – it is also a decision of the United States Court of Appeals for the District of Columbia Circuit. The D.C. Circuit held:

Once a distributor has reported a suspicious order, it must make one of two choices: decline to ship the order, or conduct some “due diligence” and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order.²⁰

The underlying *Masters* DEA adjudication and the *Southwood* decision are agency adjudications, but they, too, are legal precedents and agency rulings entitled to deference in this Court. In *Southwood*, the DEA held that the failure to perform

¹⁷ See *In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3917575, at *7-9 (N.D. Ohio Aug. 19, 2019); *City and County of San Francisco v. Purdue Pharma, LP, et al.*, No. 3:18-CV-07591-CRB, 2020 WL 5816488 at *3-4 (N.D. Cal. Sep. 30, 2020).

¹⁸ See *Masters Pharmaceuticals Inc., Decision and Order*, 80 FR 55418-01, 2015 WL 5320504 (DEA September 15, 2015), *aff'd*, *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213, 222 (D.C. Cir. 2017); *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 2007 WL 1886484 (DEA July 3, 2007). The *Masters* and *Southwood* adjudications are discussed in detail in Plaintiffs' opening memorandum, at p. 6-10.

¹⁹ See Opp. at 13-15.

²⁰ 861 F.3d at 212-213.

proper due diligence and to halt suspicious orders constituted a failure to maintain effective controls against diversion warranting (among other factors), revocation of Southwood's registration.²¹ In *Masters*, the DEA specifically affirmed the "due diligence" requirement, holding that

a distributor's duty to perform due diligence on its customers stems from the requirement that a registrant "shall provide effective controls and procedures to guard against theft and diversion of controlled substances," 21 CFR 1301.71(a), as well as the registration requirements of section 823, which, in the case of a distributor, direct the Agency, in making the public interest determination, to consider the "maintenance of effective controls against diversion of particular controlled substances into other than legitimate medical . . . channels."²²

The DEA specifically rejected the argument that the "due diligence" requirement was inapplicable because it had been announced in an agency adjudication, rather than through rule-making, noting that "[t]he Supreme Court...long ago rejected the contention that an agency must announce all rules it adopts only through notice and comment rulemaking."²³

Defendants devote much ink to the specifics of the *Southwood* and *Masters* cases, and to their contention that their holdings are limited to their facts. But Plaintiffs do not argue that Defendants' registrations must be revoked under the reasoning of *Southwood* and *Masters*, only that these adjudications reflect the

²¹ See 72 FR at 36498-99. The DEA held that "because registrants have a general duty to maintain effective controls against diversion, *they may not ignore indicators of diversion*. . . ." *Id.* at 36,500.

²² 80 FR at 55477.

²³ *Id.* at 55476 (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 290-95 (1974) and *SEC v. Chenery Corp.*, 332 U.S. 194, 199-204 (1947)).

requirement inherent in the CSA that effective control requires that registrants suspend shipments of suspicious orders until it can be determined through due diligence that diversion is unlikely. In the end, however, Defendants concede that agency determinations like *Southwood* and *Masters* are “interpretive precedent[s].”²⁴ Put another way, these decisions are equivalent to case-law construing or interpreting the CSA to impose a duty to suspend shipments pending investigation of suspicious orders. This Court should similarly conclude that the CSA imposes this obligation.

As the Supreme Court has explained, “[t]he well-reasoned views of the agencies implementing a statute constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance.”²⁵ Indeed, the Supreme Court has held that “we have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer.”²⁶ Although it is true that the DEA must determine, on a case-by-case basis, whether a grant or continuation of a registration is consistent with the public interest, and whether a particular registrant has complied with its statutory or regulatory obligations, it is also true that the DEA is

²⁴ See Opp. at 14.

²⁵ *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001).

²⁶ Opening Brief, at 12 (citing *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)); see also *Nat'l Elec. Mfrs. Ass'n v. U.S. Dep't of Energy*, 654 F.3d 496, 504 (4th Cir. 2011) (“If, however, ‘the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute.’” (quoting *Chevron*, 533 U.S. at 843)).

empowered to determine, as a matter of law, that particular types of practices are inconsistent with the maintenance of effective controls against diversion and thus do not meet the requirements of the statute and the regulations.

Although the Supreme Court considers a variety of factors in determining the degree of deference to accord an agency determination, a “good indicator” that such deference is warranted is “express congressional authorization[] to engage in the process of rulemaking or adjudication that produces regulations or rulings for which deference is claimed.”²⁷ Indeed, *Mead* makes it clear that formal adjudication stands on the same footing as notice-and-comment rulemaking with respect to the deference courts accord to agency findings.²⁸

The Controlled Substances Act provides exactly such express authorization and formalized procedure: section 824 specifically empowers the Justice Department to suspend or revoke registrations, precisely what occurred in *Southwood* and *Masters*. And, *Southwood* and *Masters* are carefully reasoned, formal adjudications reflecting both exceptional thoroughness and expertise on the part of the DEA. All these factors point toward substantial deference to the agency’s

²⁷ *Mead*, 533 U.S. at 229; *see also Varsity Brands, Inc. v. Star Athletica, LLC*, 799 F.3d 468, 478 (6th Cir. 2015) (deference to an agency interpretation warranted when “Congress provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force”), *aff’d*, 137 S. Ct. 1002 (2017).

²⁸ 533 U.S. at 230. The Defendants argue that in the past the DEA has used notice and comment rulemaking to impose a no shipping requirement. Opp. at 10. Of course, as *Mead* makes clear, both formal adjudications and rulemaking stand on equal footing; as such, the use in the past of one of these procedures to announce agency findings does not bar the use of the alternative in another instance. And adjudication is an appropriate avenue when, as is the case here, the agency is construing what the law is rather than imposing new obligations.

determination that controls against diversion cannot be effective if a registrant continues to ship orders it knows to be suspicious.

B. The No-Shipping Duty Is Inherent in the Requirement to Maintain Effective Controls against Diversion.

If this Court gives no weight to *Masters or Southwood*, it can and should *still* find that Defendants were obliged to halt shipments of suspicious orders until it could be determined, through due diligence, that the orders were unlikely to be diverted. Even if it writes on a blank slate, this Court should construe the CSA and its regulations to determine the scope of the duties imposed by the regulatory scheme. As discussed above and in Plaintiffs' opening brief, the no-shipping duty follows inexorably from the explicit regulatory commands to maintain effective controls against diversion and to identify suspicious orders. How can controls against diversion possibly be effective if registrants are free to ship orders the DEA has defined, and registrants themselves have identified, as suspicious, without first investigating the likelihood of diversion? If the only purpose in identifying suspicious orders was to report them to the DEA, what would be the point of Defendants' affirmative obligation to maintain effective controls against diversion?

As Judge Polster persuasively concluded:

In sum, the Court concludes that the CSA statutory and regulatory duties to maintain effective controls against diversion includes a duty not to ship suspicious orders. Indeed, given the overriding duty of a registrant to maintain effective controls against diversion, the Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot.

It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.²⁹

Defendants' vision of the statutory and regulatory scheme – in which registrants simply identify and report suspicious orders, but all other steps to control diversion fall solely on the DEA – is flatly inconsistent with the DEA's explicit requirement that the *registrants* themselves must maintain effective controls over the supply chain. It is also inconsistent with a closed system that involves many thousands of participants and thus many thousands of potential diversion points.³⁰ Only by enlisting all of those many thousands of participants to keep watch can the DEA hope to control a supply chain involving so many parties.³¹ That is what the DEA regulations do – they require registrants to become part of the enforcement scheme, not merely to serve as passive information gatherers who can blithely ship controlled substances they know are likely to be diverted for as long as they can get away with it.

Finally, the Defendants' arguments to the contrary, ignore the very nature of products they were distributing. As the Supreme Court noted almost eighty years ago:

²⁹ *In re Nat'l Prescription Opiate Litig.*, No. 1:17-MD-2804, 2019 WL 3917575, at *9 (N.D. Ohio Aug. 19, 2019).

³⁰ *See United States v. Moore*, 423 U.S. 122, 135 (1975) ("Congress was particularly concerned with the diversion of drugs from legitimate channels to illegitimate channels . . . [and] was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic.").

³¹ Even if no prior decisions established this, Defendants can hardly complain that they had no notice of these duties, as both *Masters* and *Southwood*, along with the "Dear Registrant" letters, put them on notice. Whether or not DEA's repeated announcements were binding, Defendants disregarded them at their peril.

The difference is like that between toy pistols or hunting rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the same susceptibility to harmful and illegal use. Nor, by the same token, do all embody the same capacity, from their very nature, for giving the seller notice the buyer will use them unlawfully. Gangsters, not hunters or small boys, comprise the normal private market for machine guns. So drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade.³²

As Judge Polster and Judge Breyer both found, there can be no effective controls against diversion if a registrant is permitted to ship orders that it knows bear the indicia of likely diversion.³³ Defendants cannot credibly argue that shipping suspicious orders is consistent with its duty to maintain effective controls against diversion because there is some possibility that the orders that they identified as unusual size, frequency, or pattern might somehow be legitimate when it conducts no investigation prior to shipping.³⁴

C. The SUPPORT Act Does Not Refute the Existence of the No-Shipping Duty.

Defendants argue that Congress's failure to include an affirmative statement of the no-shipping requirement in the 2018 SUPPORT Act demonstrates that no such requirement exists.³⁵ They further characterize the provision of the act relied on by Plaintiffs in their opening brief, PL 115-271, § 3272, as a "background note

³² *Direct Sales Co. v. United States*, 319 U.S. 703, 710, 63 S. Ct. 1265, 1269, 87 L. Ed. 1674 (1943).

³³ *See supra* note 1.

³⁴ Elsewhere, Cardinal Health raises an ill-founded concern over interrupting the supply to legitimate customers. Doc. 1087 at 20. Defendants presumably now are complying with the no-shipping duty. Defendants do not provide any evidence that the required due diligence interrupts the supply of opioids to legitimate customers.

³⁵ Opp. at 11.

related to a different provision in the 2018 amendments.”³⁶ But Chapter 7, in which this provision is found, is entitled the “Using Data to Prevent Opioid Diversion Act of 2018,” PL 115-271, § 3271, a title that makes clear the relevance of the chapter to the issues presented on this motion. Section 3272, which sets forth the purpose of the chapter, is not a “background note”; it is a section of a public law duly enacted by Congress. The next section makes ARCOS data available to registrants to assist them in preventing opioid diversion. PL 115-271, § 3273. The reason for providing this information is clearly spelled out in the Public Law itself: it is “to help drug manufacturers and distributors identify, report, *and stop* suspicious orders of opioids and reduce diversion rates.” *Id.* at § 3272(a) (emphasis added).

Moreover, as set forth in Plaintiffs’ opening brief, the statute includes a rule of construction whereby Congress recognized that the responsibility to stop suspicious orders already existed and went out of its way to provide that the receipt of ARCOS data did not *absolve* registrants of that obligation.³⁷ Why would it have been necessary (or even sensible) for Congress to explicitly state that the new information would not absolve Defendants of an obligation they did not have in the first place? That new proposed legislation appears to assert that no such obligation exists is irrelevant – the proposed legislation has not been enacted and the understanding of its drafters (whoever they may be) about the scope of duties under the CSA cannot be presumed to be Congress’s or the DEA’s.

³⁶ *Id.* at note 15.

³⁷ Opening Brief at 10-11.

D. Defendants' Evidence of Prior DEA Inspection and/or Purported Approval of Their SOM Programs Does Not Create a Triable Issue About the Scope of CSA's Requirements

Defendants seek to turn a legal question – what duties does the CSA impose on registrants – into a factual one by arguing that, even if the no-shipping duty exists now, it did not exist – or did not apply to them – prior to 2007.³⁸ But this is a *legal* question, not a factual one.³⁹ Even if this evidence accurately described the communications of certain DEA officials to a particular Defendant, it would not create a fact issue as to the scope of Defendants' duties under the CSA.⁴⁰ Nor, as discussed below, does it provide a basis for the Court to reach a different conclusion about those duties than the one reached by the D.C. Circuit, Judge Polster and Judge Breyer.

The Court may consider what the DEA said and did in construing DEA regulations, just as it may consider legislative history in construing a statute, but consideration of extrinsic evidence as an aid in construction does not convert a legal question for the Court into a factual question for a jury.⁴¹ Contrary to Defendants'

³⁸ See Opp. at 16-19.

³⁹ *Id.*

⁴⁰ *Cf.* MDL Doc. 2494 at 7 (Judge Polster noting that witnesses “may not opine as to what the law requires”). Furthermore, Defendants have ***not even alleged*** that they meet the high standard necessary to establish governmental estoppel. *United States v. VanHorn*, 20 F.3d 104, 112 n.19 (4th Cir. 1994) (“Federal law is clear that estoppel is rarely, if ever, a valid defense against the Government absent proof of some affirmative misconduct by a Government agent[.]”); *see also Masters Pharm.*, 861 F.3d at 225 (2017) (same).

⁴¹ See *Cowpasture River Pres. Ass'n v. Forest Serv.*, 911 F.3d 150, 183 (4th Cir. 2018) (“statutory interpretation . . . is the peculiar province of the courts”), *rev'd and remanded on other grounds*, 140 S. Ct. 1837 (2020).

suggestion, Judge Polster did not find that “evidence that the DEA did not impose a no-ship requirement before 2008 presented issues for a jury determination.”⁴² Indeed, in his December 26, 2019 Order, Judge Polster expressly rejected that characterization of his prior SOM’s order: “In fact, the Court held that material issues of fact existed as to whether defendants had violated or not substantially complied with their duties under the CSA – not whether the duties themselves had always existed or changed over time.”⁴³ Consequently, Judge Polster granted Plaintiffs’ motion in limine and precluded “arguments that the CSA and its implementing regulations do not impose, *or have not always imposed*, duties on registrants to identify, report, and not ship suspicious orders.”⁴⁴

Nor, in any event, are Defendants correct about the significance of the DEA statements on which they rely. The DEA has repeatedly told “every entity in the United States registered with the [DEA] to manufacture or distribute controlled substances” that the “regulation clearly places the responsibility on the registrant to design and operate [a SOM] system[,]” and thus, “DEA does not approve or otherwise endorse any specific system for reporting suspicious orders.”⁴⁵ Moreover, in December 2007, DEA informed all registrants that any “past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to

⁴² Opp. at 16, n.20 (citing *In re Nat’l. Prescription Opiate Litig.*, 2019 WL 3917575, at *15).

⁴³ MDL Doc. 3052 at p. 25 n.49 (Exhibit 2).

⁴⁴ *Id.* at p. 25 (emphasis added).

⁴⁵ 2007 DEA Letter at p. 1 (Opening Brief, Exhibit D).

mean that DEA approves a specific system."⁴⁶

But even prior to December 2007, to the extent any Defendant claims that it could not have violated the CSA because the DEA specifically approved its SOM system in direct communications with that Defendant, such purported approval fails to create a triable issue of fact. An administrative agency's purported pre-approval of conduct cannot exempt an entity from clear violations of a law.⁴⁷ As a matter of black-letter law, in the event an agency actually does express pre-approval of illegal conduct, Title 5, section 706 of the United States Code obligates a reviewing court to set aside and invalidate any such approval.⁴⁸ According to §706, a reviewing court "shall"⁴⁹ determine the applicability of an agency action, and set aside the agency's actions, findings, or conclusions, if they are found to be "not in accord with the law."⁵⁰

⁴⁶ *Id.*

⁴⁷ Indeed, the idea that the DEA could pre-approve any Defendants' conduct as lawful here is as preposterous as the idea that a police officer could pre-authorize someone's murder.

⁴⁸ 5 U.S.C. § 706 ("To the extent necessary to decision and when presented, the reviewing court *shall decide all relevant questions of law, interpret constitutional and statutory provisions*, and determine the meaning or applicability of the terms of an agency action. The reviewing court *shall...*(2) *hold unlawful and set aside agency action, findings, and conclusions found to be – (A) . . . not in accordance with law; . . . (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right*").

⁴⁹ "Section 706 is mandatory by its terms and not merely declarative of 'guidelines' with respect to the scope of judicial review of a federal agency's action." *Charlton v. United States*, 412 F.2d 390, 392 (3d Cir. 1969).

⁵⁰ *Id.*

Courts may not disregard the plain text of a statute in favor of a contradictory administrative opinion.⁵¹ Under the *Chevron* deference analysis, "a court will not defer to an agency's construction if it is 'arbitrary, capricious or manifestly contrary to the statute.'"⁵² Moreover, the agency must have supplied a "satisfactory explanation" for its action.

Defendants go to great lengths to argue that the Rannazzisi letters do not constitute official rulemaking or adjudications of the DEA⁵³ and, as discussed above, attempt even to dismiss the DEA's formal adjudications as without precedential effect. But however mistaken this argument may be with respect to the *Masters and Southwood* decisions, which are formal DEA adjudications, the point is well taken with respect to any unauthorized, *ad hoc* pronouncements of DEA field agents regarding any of Defendants' SOM systems.

The scope of duties imposed by the CSA is a legal question to be determined by the Court through construction of the statute and its implementing regulations, giving due deference to the official findings and adjudications of the DEA, the agency charged with implementing the regulatory scheme. Individual statements of

⁵¹ See *Athan v. United States Steel*, 364 F.Supp. 3d 748, 755 (E.D. Mich. 2019).

⁵² *Averett v. United States Dep't of Health & Human Servs.*, 306 F.Supp 3d 1005, 1012 (M.D. Tenn. 2018). See also *Thomas v. Abercrombie & Fitch Co.*, 301 F.Supp. 3d 749, 758-59 (E.D. Mich. 2018); *Hughes Air Corp. v. C.A.B.*, 482 F.2d 143, 145-146 (9th Cir. 1973) (setting aside agency action the court found to be "clearly wrong.").

⁵³ See Opp. at 12-13.

DEA agents cannot and do not alter the contours of those duties.⁵⁴ Moreover, the *failure* of DEA agents to take action has even less value (if it possible to have less value than none) in assessing what it is the CSA and its regulations require of the Defendants.⁵⁵

III. PLAINTIFFS' PUBLIC NUISANCE CLAIMS ARE NOT PREEMPTED.

The Defendants contend that Plaintiffs' claims are preempted, arguing that imposing common law tort liability for public nuisance would conflict with the CSA.⁵⁶ This argument was previously raised by Defendants in the MDL and was rejected.⁵⁷ The same argument was also raised as part of Defendants' Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims.⁵⁸ For the reasons stated in Plaintiff's Memorandum in Opposition to Joint

⁵⁴ In many instances the statement of the DEA on which Defendants rely are flatly contradicted by DEA enforcement actions as well as by Defendants' own admissions, in the context of settling those actions, that they had failed to comply with the CSA.

⁵⁵ Defendants cite *U.S. v. \$463,497.72*, 853 F.Supp. 2d 675 (E.D. Mich. 2012) in support of their contention that the DEA was aware that it was standard practice in the industry to file suspicious order reports while continuing to ship products and that practice has been approved by the DEA, *see* Opp. at 19, fn. 30. Even if the testimony cited in that case were competently offered in this case – which it is not— at most it would establish knowledge of registrants' practices on the part of particular agents; it would not alter the legal contours of the registrants' duties.

⁵⁶ Opp. at 19-20.

⁵⁷ *See* MDL Doc 2565 at 22 ("The Court finds that Plaintiff's state law claims are not preempted"); at 12 ("The Court has previously rejected this obstacle preemption argument, albeit with respect to the FDA, and now does so with respect to the DEA"); (Exhibit 3); *City of San Francisco v. Purdue Pharma, LP, et al.*, 2020 WL 5816488 at *28-29 (Sep. 30, 2020) (Finding that the "CSA's provisions demonstrate that state tort actions pose no obstacle to its goals and DEA enforcement")(Exhibit 1).

⁵⁸ Doc. 1007 at 13-17.

Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims, Plaintiffs' claims do not conflict with federal law and are not preempted.⁵⁹ As Judge Polster found, Plaintiffs' public nuisance claims are not preempted because the state-law claims would not impede "the DEA's ability to regulate and enforce the CSA."⁶⁰ Rather than interfere with the CSA, the Plaintiffs' claims are of the type specifically contemplated by it: the CSA welcomes enforcement of state law to supplement the federal enforcement scheme.⁶¹

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant Plaintiffs' Motion for Partial Summary Adjudication of Defendants' Duties Under the Controlled Substances Act and hold that Defendants had the duties under the CSA and its implementing regulations to design and operate a system to disclose to the suspicious orders, inform the DEA of suspicious orders when discovered, and to not to ship suspicious orders without performing due diligence.

⁵⁹ Doc. 1075 at 16-19.

⁶⁰ *In re Nat'l Prescription Opiate Litig.*, 1:17-MD-2804, 2019 WL 4178591, at *6, 12 (N.D. Ohio Sept. 3, 2019).

⁶¹ *See* 72 FR 52717, fn. 13 (Sep. 6, 2006) ("Congress expressly intended that there would be a dual system of Federal-state regulation of controlled substances by including in the CSA a preemption provision, 21 U.S.C. 903, which reflects that this field of regulation was to be shared by the Federal and state governments.") (Exhibit 4).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 30, 2020, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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